UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,530	01/14/2002	Scott P. Bruder	640100-440	5553

27162 7590 02/08/2005

CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI,
STEWART & OLSTEIN
5 BECKER FARM ROAD
ROSELAND, NJ 07068

EXAMINER	
LI, QIAN JANICE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,530	BRUDER ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 6-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-13 and 16* is/are rejected.

7)☒ Claim(s) *14, 15, 17-19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment, response, and terminal disclaimer filed on August 27, 2004 have been entered. The Examiner assigned to examine your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Q. Janice Li, at Group Art Unit 1632.

Currently, claims 1, 2, and 6-19 are pending and under examination. Claims 1, 2, 6-12, 14, 17, and 18 have been amended, and claims 3-5 have been canceled.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims, arguments, and terminal disclaimer will not be reiterated.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, and 6-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-25 of U.S. Patent No. 6,368,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the claims of the cited patent are drawn to using the culture supernatant of mesenchymal stem cells, the specification clearly teaches administering said cells is the alternative for the supernatants (e.g. see abstract and column 2). Accordingly, the subject matter is fully disclosed in the cited patent.

Therefore, claims of the present application and the cited patent are obvious variants, and co-extensive.

Claims 1, 2, and 6-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,328,960. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims have overlapping scopes with the cited patent.

Therefore, claims of the present application and the cited patent are obvious variants, and co-extensive.

Claims 1, 2, and 6-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8-10

of U.S. Patent No. 6,797,269. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are drawn to administering genetically modified MSCs to a host for inhibiting an immune response to an antigen, and thus the instant claims have overlapping scopes with the cited patent.

Therefore, claims of the present application and the cited patent are obvious variants, and co-extensive.

Claims 1, 2, and 6-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent Application No. 10/067,121 (US 2002/0085996), now allowed.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the cited patent are drawn to suppressing immune response in xenograft transplantation using mesenchymal stem cells, but it would have been obvious to the skilled artisan, and the specification clearly teaches, that said cells would have been applicable in allogenic transplantation (e.g. see abstract).

Therefore, claims of the present application and the allowed application are obvious variants, and co-extensive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by *Abatangelo et al* (US 6,482,231).

Abatangelo et al teach a method for repairing connective tissue by introducing into a site of a patient in need thereof a composition comprising an enriched preparation of mesenchymal stem cells and a three dimensional matrix carrier (e.g. claims 15 and 16); wherein the connective tissue includes muscle cells (e.g. column 8, line 4), the donor mesenchymal stem cells could be allogenic (e.g. column 5, line 67), and harvested from a human subject (e.g. column 6, line 13). Accordingly, *Abatangelo et al* anticipate instant claims.

Claims 1, 2, and 6-10 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The instant claims are obvious variants of claims of U.S. patents 6,368,636; 6,328,960; 6,797,269; and allowed U.S. patent application 10/067,121, as discussed in detail *supra*. Each of

the patents has a different inventive entity compared to instant application. Thus, it is unclear who is the real inventor.

It is noted instant application and the cited patents have a common assignee and inventor. The above rejection under this provision applies because there is no showing on record of common ownership at time of applicant's invention. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned patents, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Abatangelo et al* (US 6,482,231) as applied to claims 11-13 above, and further in view of *Gerson et al* (US 5,591,625).

The teachings of *Abatangelo et al* has been discussed in detail *supra*, *Abatangelo et al* did not teach to incorporate genetic materials in the mesenchymal stem cells.

Gerson et al supplemented the teaching of *Abatangelo et al* by establishing that it is well known in the art to use MSCs expressing a therapeutic gene for clinical treatment (see entire document and e.g. example 3).

Accordingly, it would have been obvious to one of ordinary skilled in the art to combine the teachings of *Abatangelo et al* and *Gerson et al* by transducing MSCs with a gene of interest as taught by *Gerson et al* in the method as taught

by *Abatangelo et al* with a reasonable expectation of success. The ordinary skilled in the art would have been motivated to do so for enhanced therapeutic benefit of the transduced MSCs. Thus, the claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the cell preparation" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

Claim 1 is objected to because the article “the” should be inserted in place of “a” in lines 9 and 10 before “recipient”.

Claims 2, 6-10, 12-16, 18, and 19 are objected to because a comma should be inserted following “The method of claim x”.

Claim 6 is objected to because the word “recipient” should be inserted before “mammal” in line 3.

Claim 11 is objected to because the article “the” should be inserted in place of “a” in line 7 before “recipient”.

Claim 17 is objected to because the word "tissue" should be inserted before "surface in line 3; the article "the" should be inserted in place of "a" in line 4 before "recipient"; and the word "stem" should be inserted before the first "cells" in line 5.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Ram R. Shukla** can be reached on 571-272-0735. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the

specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Q. Janice Li
Primary Examiner
Art Unit 1632

QJL
February 1, 2005